ROBOSCREEN
DIAGNOSTICS

Declaration of conformity

Name and adress of Manufacurer:	Roboscreen GmbH Hohmannstrasse 7 04129 Leipzig, Germany
SRN of Manufacturer:	DE-MF-000024661

The **Roboscreen GmbH** declares on own responsibility that the medical device

Name:	Rapid INSTANT Virus RNA/DNA Kit - FX
Catalogue number:	847-0259200906
Description:	Automated extraction of viral nucleic acids by means of magnetic particles
Basic-UDI-DI:	4262386730259222J2
Risk class:	Class A

meets all applicable requirements of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices. In the context of conformity with the mentioned regulation the standards referred to in Chapter 4.1 of the Technical Documentation have been fully or partially applied.

Applied conformity assessment procedure:	Annex II (Technical Documentation) and Annex III (Post-market surveillance)
Applied CS:	None
Name and referenc number of notified body:	Not applicable
Certificate issued by the notified body:	Not applicable
Validity (DD.MM.YYYY):	02.05.2024 – 01.05.2025
Place:	Leipzig
Date:	02.05.2024
Name and Function:	Dr. Ingolf Lachmann, CEO
Legally binding signature:	

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